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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
JOYCE, CATHERINE	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/670,472	MA ET AL.	
	Examiner	Art Unit	
	Catherine M. Joyce	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-44 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   1. Claims 1-4 and 28-31, as drawn to an isolated peptide consisting of an amino acid sequence of ALKDVEERX (SEQ ID No:1), classified in class 530, subclass 300.

   2. Claims 1, 3, 4, and 28-31, as drawn to an isolated peptide consisting of an amino acid sequence of LKDVEERV (SEQ ID No:2), classified in class 530, subclass 300.

   3. Claims 1, 3, 4, and 28-31 as drawn to an isolated peptide consisting of an amino acid sequence of LFGLALIEV (SEQ ID No:78), classified in class 530, subclass 300.

   4. Claims 1, 3, 4, and 28-31, as drawn to an isolated peptide consisting of an amino acid sequence of XLFGLALIEV (SEQ ID No:88), classified in class 530, subclass 300.

   5. Claims 5-10, as drawn to an isolated nucleic acid molecule that encodes an isolated peptide consisting of an amino acid sequence of ALKDVEERX (SEQ ID No:1), classified in class 536, subclass 23.1.

   6. Claims 5-10, as drawn to an isolated nucleic acid molecule that encodes an isolated peptide consisting of an amino acid sequence of LKDVEERV (SEQ ID No:2), classified in class 536, subclass 23.1.

7. Claims 5-10, as drawn to an isolated nucleic acid molecule that encodes an isolated peptide consisting of an amino acid sequence of LFGLALIEV (SEQ ID No:78), classified in class 536, subclass 23.1.

8. Claims 5-10, as drawn to an isolated nucleic acid molecule that encodes an isolated peptide consisting of an amino acid sequence of XLFGLALIEV (SEQ ID No:88), classified in class 536, subclass 23.1.

9. Claim 11, as drawn to a method for determining if a cell presents an HLA-A2 molecule on its surface comprising contacting a sample containing the cell with an isolated peptide consisting of an amino acid sequence of ALKDVEERX (SEQ ID No:1), classified in class 435, subclass 4.

10. Claim 11, as drawn to a method for determining if a cell presents an HLA-A2 molecule on its surface comprising contacting a sample containing the cell with an isolated peptide consisting of an amino acid sequence of LKDVEERV (SEQ ID No:2), classified in class 435, subclass 4.

11. Claim 11, as drawn to a method for determining if a cell presents an HLA-A2 molecule on its surface comprising contacting a sample containing the cell with an isolated peptide consisting of an amino acid sequence of LFGLALIEV (SEQ ID No:78), classified in class 435, subclass 4.

12. Claim 11, as drawn to a method for determining if a cell presents an HLA-A2 molecule on its surface comprising contacting a sample containing the cell with an isolated peptide consisting of an amino acid sequence of XLFGLALIEV (SEQ ID No:88), classified in class 435, subclass 4.

13. Claim 12, as drawn to a composition comprising an isolated peptide consisting of an amino acid sequence of ALKDVEERX (SEQ ID No:1), an adjuvant , and at least one additional peptide, classified in class 530, subclass 300.

14. Claim 12, as drawn to a composition comprising an isolated peptide consisting of an amino acid sequence of LKDVEERV (SEQ ID No:2), an adjuvant , and at least one additional peptide, classified in class 530, subclass 300.

15. Claim 12, as drawn to a composition comprising an isolated peptide consisting of an amino acid sequence of LFGLALIEV (SEQ ID No:78), an adjuvant , and at least one additional peptide, classified in class 530, subclass 300.

16. Claim 12, as drawn to a composition comprising an isolated peptide consisting of an amino acid sequence of XLFGLALIEV (SEQ ID No:88), an adjuvant , and at least one additional peptide, classified in class 530, subclass 300.

17. Claims 13-16 as drawn to a polytope comprising at least two peptides linked together wherein at least one the peptides is an isolated peptide consisting of an amino acid sequence of ALKDVEERX (SEQ ID No:1), classified in class 530, subclass 300.

18. Claims 13-16, as drawn to a polytope comprising at least two peptides linked together wherein at least one the peptides is an isolated peptide consisting of an amino acid sequence of LKDVEERV (SEQ ID No:2), classified in class 530, subclass 300.

19. Claims 13-16, as drawn to a polytope comprising at least two peptides linked together wherein at least one the peptides is an isolated peptide consisting of an amino acid sequence of LFGLALIEV (SEQ ID No:78), classified in class 530, subclass 300.

20. Claims 13-16, as drawn to a polytope comprising at least two peptides linked together wherein at least one the peptides is an isolated peptide

consisting of an amino acid sequence of XLFGLALIEV (SEQ ID No:88), classified in class 530, subclass 300.

21. Claims 17-26 as drawn to an isolated nucleic acid molecule encoding a polytope comprising at least two peptides linked together wherein at least one the peptides is an isolated peptide consisting of an amino acid sequence of ALKDVEERX (SEQ ID No:1), classified in class 536, subclass 23.1.

22. Claims 17-26, as drawn to a an isolated nucleic acid molecule encoding polytope comprising at least two peptides linked together wherein at least one the peptides is an isolated peptide consisting of an amino acid sequence of LKDVEERV (SEQ ID No:2), classified in class 536, subclass 23.1.

23. Claims 17-26, as drawn to an isolated nucleic acid molecule encoding a polytope comprising at least two peptides linked together wherein at least one the peptides is an isolated peptide consisting of an amino acid sequence of LFGLALIEV (SEQ ID No:78), classified in class 536, subclass 23.1.

24. Claims 17-26, as drawn to an isolated nucleic acid molecule encoding a polytope comprising at least two peptides linked together wherein at least one the peptides is an isolated peptide consisting of an amino acid sequence of XLFGLALIEV (SEQ ID No:88), classified in class 536, subclass 23.1.

25. Claim 27 and 33, as drawn to a method for determining if a cytolytic T cell specific to complexes of an HLA-A2 molecule and a peptide is present in sample comprising admixing the sample with an HLA-A2 molecule and an isolated peptide consisting of an amino acid sequence of ALKDVEERX (SEQ ID No:1), classified in class 435, subclass 4.

26. Claim 27 and 33, as drawn to a method for determining if a cytolytic T cell specific to complexes of an HLA-A2 molecule and a peptide is present in sample comprising admixing the sample with an HLA-A2 molecule and an isolated peptide consisting of an amino acid sequence of LKDVEERV (SEQ ID No:2), classified in class 435, subclass 4.

27. Claim 27 and 33, as drawn to a method for determining if a cytolytic T cell specific to complexes of an HLA-A2 molecule and a peptide is present in sample comprising admixing the sample with an HLA-A2 molecule and an isolated peptide consisting of an amino acid sequence of LFGLALIEV (SEQ ID No:78), classified in class 435, subclass 4.

28. Claim 27 and 33, as drawn to a method for determining if a cytolytic T cell specific to complexes of an HLA-A2 molecule and a peptide is present in sample comprising admixing the sample with an HLA-A2 molecule and an isolated peptide consisting of an amino acid sequence of XLFGLALIEV (SEQ ID No:88), classified in class 435, subclass 4.

29. Claims 32, as drawn to a method for monitoring the status of a tumor comprising contacting sample take from a patient having a tumor with an isolated complex comprising a first and second binding partner which are specific for each other, wherein the second binding partner is bound to a plurality of tetramers of an HLA-A2 molecule, a β2 microglobulin molecule, and an isolated peptide consisting of an amino acid sequence of ALKDVEERX (SEQ ID No:1), classified in class 435, subclass 4.

30. Claim 32, as drawn to a method for monitoring the status of a tumor comprising contacting sample take from a patient having a tumor with an isolated complex comprising a first and second binding partner which are specific for each other, wherein the second binding partner is bound to a plurality of tetramers of an HLA-A2 molecule, a β2 microglobulin molecule,

and an isolated peptide consisting of an amino acid sequence of LKDVEERV (SEQ ID No:2), classified in class 435, subclass 4.

31. Claim 32, as drawn to a method for monitoring the status of a tumor comprising contacting sample take from a patient having a tumor with an isolated complex comprising a first and second binding partner which are specific for each other, wherein the second binding partner is bound to a plurality of tetramers of an HLA-A2 molecule, a β2 microglobulin molecule, and an isolated peptide consisting of an amino acid sequence of LFGLALIEV (SEQ ID No:78), classified in class 435, subclass 4.

32. Claim 32, as drawn to a method for monitoring the status of a tumor comprising contacting sample take from a patient having a tumor with an isolated complex comprising a first and second binding partner which are specific for each other, wherein the second binding partner is bound to a plurality of tetramers of an HLA-A2 molecule, a β2 microglobulin molecule, and an isolated peptide consisting of an amino acid sequence of XLFGLALIEV (SEQ ID No:88), classified in class 435, subclass 4.

33. Claims 34-42, as drawn to a method for inducing an immune response in subject comprising administering a composition comprising an effective amount of a peptide that consists of an amino acid sequence of SEQ ID NO:1, classified in class 424, subclass 184.1.

34. Claims 34-42, as drawn to a method for inducing an immune response in subject comprising administering a composition comprising an effective amount of a peptide that consists of an amino acid sequence of SEQ ID NO:2, classified in class 424, subclass 184.1.

35. Claims 34-42, as drawn to a method for inducing an immune response in subject comprising administering a composition comprising an effective

amount of a peptide that consists of an amino acid sequence of SEQ ID NO:3, classified in class 424, subclass 184.1.

36. Claims 34-42, as drawn to a method for inducing an immune response in subject comprising administering a composition comprising an effective amount of a peptide that consists of an amino acid sequence of SEQ ID NO:5, classified in class 424, subclass 184.1.

37. Claims 34-42, as drawn to a method for inducing an immune response in subject comprising administering a composition comprising an effective amount of a peptide that consists of an amino acid sequence of SEQ ID NO:88, classified in class 424, subclass 184.1.

38. Claims 34-42, as drawn to a method for inducing an immune response in subject comprising administering a composition comprising an effective amount of a peptide that consists of an amino acid sequence of SEQ ID NO:77, classified in class 424, subclass 184.1.

39. Claims 34-42, as drawn to a method for inducing an immune response in subject comprising administering a composition comprising an effective amount of a peptide that consists of an amino acid sequence of SEQ ID NO:78, classified in class 424, subclass 184.1.

40. Claims 43, as drawn to a method for treating a subject with a disorder characterized by the presence of complexes of an HLA-A2 molecule and a peptide having the amino acid sequence of SEQ ID NO:1, classified in class 424, subclass 184.1.

41. Claims 43, as drawn to a method for treating a subject with a disorder characterized by the presence of complexes of an HLA-A2 molecule and a peptide having the amino acid sequence of SEQ ID NO:2, classified in class 424, subclass 184.1.

42. Claims 43 and 44, as drawn to a method for treating a subject with a disorder characterized by the presence of complexes of an HLA-A2 molecule and a peptide having the amino acid sequence of SEQ ID NO:3, classified in class 424, subclass 184.1.

43. Claims 43 and 44, as drawn to a method for treating a subject with a disorder characterized by the presence of complexes of an HLA-A2 molecule and a peptide having the amino acid sequence of SEQ ID NO:5, classified in class 424, subclass 184.1.

44. Claims 43 and 44, as drawn to a method for treating a subject with a disorder characterized by the presence of complexes of an HLA-A2 molecule and a peptide having the amino acid sequence of SEQ ID NO:88, classified in class 424, subclass 184.1.

45. Claims 43 and 44, as drawn to a method for treating a subject with a disorder characterized by the presence of complexes of an HLA-A2 molecule and a peptide having the amino acid sequence of SEQ ID NO:78, classified in class 424, subclass 184.1.

3. The inventions are distinct, each from the other, because of the following reasons:

The inventions of groups 1-8 and 13-24 are materially distinct products with different structures and functions. For example, Groups 5-8 and 21-24 encompass nucleic acids and Groups 1-4 and 13-20 encompass polypeptides. Each of these groups represent separate and distinct products having different structures. Currently, there are approximately eight different databases that accompany the results of a search of one discrete amino acid or nucleotide sequence and each result set from a particular database must be carefully considered. Thus, searching any of groups 1-8 or 13-20 together would pose an undue search burden.

The inventions of Groups 9-12 and 25-51 are materially distinct methods which differ at least in objectives, method steps and reagents. For example, Groups 9-12 are drawn to a method for determining if a cell presents an HLA-A2 molecule on its surface, Groups 25-28 are drawn to methods for determining if a cytolytic T cell specific to complexes of an HLA-A2 molecule and an isolated peptide is present in a sample, Groups 29-32 are drawn to methods of monitoring the status of a tumor, Groups 33-39 are drawn to a method for inducing an immune response in a subject, Groups 40-45 are drawn to methods of treating a subject with a disorder characterized by the presence of complexes of an HLA-A2 molecule and a specific peptide, Groups 46-51 are drawn to a method for inducing a response by cytolytic T cells in a subject. Furthermore, each of the groups employs chemically distinct reagents to accomplish the differing objectives. Searching any of the method groups together would pose an undue search burden.

The following groups of inventions are related as product and process of use: Group 1 and Groups 9, 25, 29, 33, 35, 36, 40, 42, and 43; Group 2 and Groups 10, 26, 30, 34, and 41; Group 3 and Groups 11, 27, 31, 39, and 45; and Group 4 and Groups 12, 28, 32, 37, 38, 44. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptides of Groups 1-4 can be used in materially distinct processes such as affinity chromatography.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were

made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is

found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine M. Joyce whose telephone number is 571-272-3321. The examiner can normally be reached on Monday thru Friday, 10:15 - 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine M. Joyce
Examiner
Art Unit 1642

SUSAN UNGAR, PH.D
PRIMARY EXAMINER